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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,920	03/26/2004	Ruediger Stendel	1194-280	6751

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/809,920	STENDEL ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-19 and 21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,20,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/26/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

Claims 1-3, 20, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfirrmann US 4,587,268.

Pfirrmann teaches a composition comprising a resorbable aqueous gel having dissolved or dispersed therein one or more water-soluble medicament such as an antibacterial compound. Pfirrmann further teaches the use of such composition for healing an infection of bone or other tissue. See abstract; column 1, lines 55-68; and column 3, lines 17-23. Resorbable gel includes fibrous protein, collagen, and gelatin (column 2, lines 1-28). Antibacterial compound includes methylol transfer agents such as taurolidine or taurultam (column 3, lines 25 through column 4, lines 1-11). Pfirrmann also teaches the amount of taurolidine is from 0.5% to 5% by weight (column 4, lines 12-46).

It is noted that Pfirrmann does not explicitly teach that the system is also useful for preventing or inhibiting growth of cancer cells. However, such limitation is inherent because Pfirrmann teaches the use of the same antineoplastic agent in the claimed concentration. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

Claims 1-6, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. US 5,788,979, in view of Lehner US 6,258,797.

This rejection has been withdrawn in view of Applicant's Remarks, filed 05/26/10, at pages 10-11.

Claims 1-6, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calabresi et al. WO 0139762 A2, in view of Hiroko et al. JP 05-294849 A.

Calabresi teaches a composition comprising effective amount of taurolidine or taurultam as active agent suitable for the treatment of cancer (abstract; page 5, lines 19-24; and claims). Calabresi further teaches the active agent is to be incorporated into a slow release solution, solid, or resorbable carrier suitable for implanting (page 10, 2nd paragraph).

Calabresi does not expressly teach the claimed carrier, such as a biodegradable adhesive.

Hiroko teaches a carrier system suitable to retain in the local site to enable the slow release of the active component (abstract).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the formulation of Calabresi to prepare a formulation suitable to adhere/remain in the local site to slowly release the active agent in view of the teachings of Hiroko. This is because Hiroko teaches a formulation that is usable as an extremely excellent sustained release agent, easily applicable to the body, and enabling sustained release of the active component over a long period (abstract), and because Calabresi teaches the desirability to obtain a formulation that can remain at the local site and slowly release the active compound.

Calabresi further does not teach the claimed amount of the active agent. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Hence, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select the amount of active agent that falls within the claimed range. This is because Calabresi teaches the use of the same active agent for the same purpose, namely, using taurolidine or taurultam for the treatment of cancers.

Response to Arguments

Applicant's arguments filed 05/26/10 have been fully considered but they are not persuasive.

Applicant argues that Pfirrmann '268 does not disclose the claimed composition. Specifically, the '268 patent does not disclose the adherence aspect of the present application. The '268 patent refers to an aqueous gel formed from cross-linked fibrous proteins (column 1, lines 59-60). The gel is preferably in the form of a shaped solid such as a rod or in the form of a granulate (column 2, lines 7-11). The '268 patent continually suggests ways to make the gelatin more solid and therefore less likely to adhere. For example, adding calcium phosphate (column 3, lines 9-10), leaving the gel out to dry for longer periods of time (column 5, lines 59-64), and drying the gel in an oven to increase the firmness and granulability (column 6, lines 20-21). It is also necessary to cross-link the gel in the '268 patent to ensure the cohesion of the gel, making it a solid (column 4, lines 31-32). The '268 patent never discloses or suggests the gel as an adhesive. Rather, the teaching suggests the gel should be in the form of a rod, which does not suggest adherence, or in the form of a granulate, which teaches *away* from adherence. That is, the more granulate the gel is, the less likely it will adhere. For at least these reasons, the '268 patent cannot anticipate the present claims and thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

In response to applicant's arguments, however, the burden is shifted to applicant to show that the gel composition taught by the '268 patent does not exhibit at least similar result, namely, "*capable* of adhering to tissue of a living subject". *The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is*

based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). It is of note that the '268 patent teaches the use of the same biodegradable adhesive in the composition, such as fibrous protein, collagen, and gelatin (column 2, lines 1-28). These matrix materials are known in the art to possess adhesive properties. See for example Sawyer et al. at column 1, lines 33-50. This reference is cited solely to show that collagen, gelatin and/or fibrous are known in the art to have adhesive property. This is not a new rejection.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 05/26/10 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615